

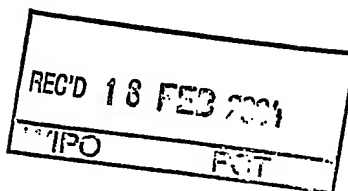


10/5550CT/EP03/13074



INVESTOR IN PEOPLE

**PRIORITY  
DOCUMENT**  
SUBMITTED OR TRANSMITTED IN  
COMPLIANCE WITH RULE 17.1(a) OR (b)



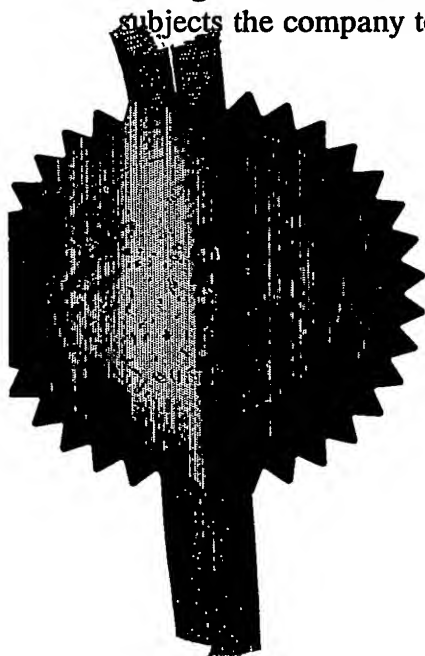
The Patent Office  
Concept House  
Cardiff Road  
Newport  
South Wales  
NP10 8QQ

I, the undersigned, being an officer duly authorised in accordance with Section 74(1) and (4) of the Deregulation & Contracting Out Act 1994, to sign and issue certificates on behalf of the Comptroller-General, hereby certify that annexed hereto is a true copy of the documents as originally filed in connection with the patent application identified therein.

In accordance with the Patents (Companies Re-registration) Rules 1982, if a company named in this certificate and any accompanying documents has re-registered under the Companies Act 1980 with the same name as that with which it was registered immediately before re-registration save for the substitution as, or inclusion as, the last part of the name of the words "public limited company" or their equivalents in Welsh, references to the name of the company in this certificate and any accompanying documents shall be treated as references to the name with which it is so re-registered.

In accordance with the rules, the words "public limited company" may be replaced by p.l.c., plc, P.L.C. or PLC.

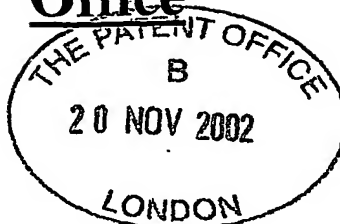
Re-registration under the Companies Act does not constitute a new legal entity but merely subjects the company to certain additional company law rules.



Signed

Dated 12 August 2003

The  
Patent  
Office



21N0002 E765109-1 D02029  
P01/7700 0.00-0227128.6

1/77

**Request for grant of a patent**

(See the notes on the back of this form. You can also get an explanatory leaflet from the Patent Office to help you fill in this form)

The Patent Office  
Cardiff Road  
Newport  
Gwent NP9 1RH

1. Your reference

JNR/PMS/P33149

2. Patent application number

(The Patent Office will fill in his part)

0227128.6

20 NOV 2002

3. Full name, address and postcode of the or of each applicant (underline all surnames)

Glaxo Group Limited  
Glaxo Wellcome House, Berkeley Avenue,  
Greenford, Middlesex UB6 0NN, Great Britain

Patents ADP number (if you know it)

If the applicant is a corporate body, give the country/state of its incorporation

United Kingdom

47387003

4. Title of the invention

A Capsule

5. Name of your agent (if you have one)

Corporate Intellectual Property

"Address for service" in the United Kingdom to which all correspondence should be sent  
(including the postcode)

GlaxoSmithKline  
Corporate Intellectual Property (CN9 25.1)  
980 Great West Road  
BRENTFORD  
Middlesex TW8 9GS

Patents ADP number (if you know it)

7960982003

6. If you are declaring priority from one or more earlier patent applications, give the country and the date of filing of the or each of these earlier applications and (if you know it) the or each application number

Country      Priority application number      Date of filing  
(if you know it)      (day / month / year)

7. If this application is divided or otherwise derived from an earlier UK application, give the number and the filing date of the earlier application

Number of earlier application      Date of filing  
(day / month / year)

8. Is a statement of inventorship and of right to grant of a patent required in support of this request? (Answer yes if:

- a) any applicant named in part 3 is not an inventor, or
  - b) there is an inventor who is named as an applicant, or
  - c) any named applicant is a corporate body
- See note (d)

# Patents Form 1/77

9. Enter the number of sheets for any of the following items you are filing with this form.  
Do not count copies of the same document

Continuation sheets of this form	0
Description	6
Claim(s)	5
Abstract	1
Drawings	2

10. If you are also filing any of the following, state how many against each item.

## Priority Documents

Translations of priority documents

Statement of inventorship and right to grant of a patent (*Patents Form 7/77*)

Request for preliminary examination and search (*Patents Form 9/77*)

Request for substantive examination (*Patents Form 10/77*)

Any other documents  
(please specify)

11.

We request the grant of a patent on the basis of this application

Signature

J N Rice

Date 20-Nov-02

12. Name and daytime telephone number of person to contact in the United Kingdom

J N Rice 01279 644508

## Warning

*After an application for a Patent has been filed, the Comptroller of the Patent Office will consider whether publication or communication of the invention should be prohibited or restricted under Section 22 of the Patents Act 1977. You will be informed if it is necessary to prohibit or restrict your invention in this way. Furthermore, if you live in the United Kingdom, Section 23 of the Patents Act 1977 stops you from applying for a patent abroad without first getting written permission unless an application has been filed at least six weeks beforehand in the United Kingdom for a patent for the same invention and either no direction prohibiting publication or communication has been given, or any such direction has been revoked.*

## Notes

- If you need help to fill in this form or you have any questions, please contact the Patent Office on 0645 500505
- Write your answers in capital letters using black ink or you may type them.
- If there is not enough space for all relevant details on any part of this form, please continue on a separate sheet of paper and write "see continuation sheet" in the relevant part(s). Any continuation sheet should be attached to this form.
- If you have answered 'Yes' Patents Form 7/77 will need to be filed.
- For details of the fee and ways to pay please contact the Patent Office.

## A Capsule

### Field of the Invention

5           The present invention relates to a capsule for holding a powder and is particularly, but not exclusively, concerned with such a capsule for containing a pharmaceutical powder, for instance an inhalable pharmaceutical powder.

### Background of the Invention

10

          Dry powder inhalation devices ("DPI" for short) are well established for use in treating respiratory diseases. As an example, there may be mentioned the DISKUS® device of GlaxoSmithKline. In general, the pharmaceutical composition is formulated as a respirable powder and the powder is divided into a plurality of unit doses, each dose contained in its own sealed enclosure, for example blisters on a dosing strip. In use of the inhaler, the enclosures are opened, one at a time, by an opening mechanism of the inhalation device and the powder dose entrained into a patient's respiratory tract by an airflow generated through the device by the patient inhaling at a mouthpiece of the device.

20

          Some of the sealed enclosures used in DPIs are difficult to fill with a unit dose of the pharmaceutical powder. It is an aim of the invention to provide a capsule for holding a powder which facilitates its filling with the powder.

### Summary of the Invention

25           According to the present invention there is provided a capsule for a powder having a body which is provided with an internal chamber to hold the powder and first and second openings to an exterior environment, the body adapted to be displaced from a filling state, in which the first and second openings are placed in fluid communication with one another through the internal chamber thereby enabling a vacuum to be applied at the first opening to create an airflow through the body from the second opening to the first opening which is

30

able to entrain powder in the exterior environment into the internal chamber for filling thereof, to a sealing state in which the internal chamber is sealed from the exterior environment so as to retain the powder held therein.

Preferred features of the invention are set forth in the subordinate claims appended hereto, as well as in the non-limiting exemplary embodiment of the invention hereinafter described with reference to the accompanying FIGURES of drawings.

#### Brief Description of the Drawings

FIGURE 1 is a part sectional side view of a capsule for a powder product in accordance with the present invention in a filling position, the capsule comprising a sleeve part and a piston part slidably mountable in the sleeve part.

FIGURE 2 is a cross-sectional view of the piston part showing a circumferential array of longitudinal channels formed in a portion of the outer surface of the piston part.

FIGURE 3 is a part sectional side view of the capsule showing the piston part in a sealed position in the sleeve part with the powder product contained in a sealed chamber defined between the piston and sleeve parts.

FIGURE 4 is a part sectional side view of the capsule with the piston part in a discharge position relative to the sleeve part.

#### Detailed Description of the Exemplary Embodiment of the Invention

In the FIGURES of drawings there is shown a generally cylindrical capsule 1 adapted to be filled with a powder product 2. The capsule 1 has particular application for dry powder products, more particularly dry powder pharmaceutical formulations for inhalation by a patient. The capsule 1 may be used in a dry powder inhaler.

The capsule 1 has a two-part construction comprising a generally cylindrical outer sleeve part 3 and a generally cylindrical inner piston part 5. The capsule 1 is preferably made from air- and moisture-proof materials, especially if the powder 2 is hygroscopic, as is the case with many pharmaceutical powders.

The outer sleeve part 3 has an annular wall 8 having an outer circumferential surface 9 and an inner circumferential surface 11. The inner circumferential surface 11 bounds an axial bore 13 which passes through the sleeve part 3 from an upper open end 15 to a lower open end 17. The upper open end 15 has a countersunk entrance 27.

The inner circumferential surface 11 is shaped to define a restriction 19 in the bore 13 to divide the bore 13 into an upper section 21 and a lower section 23. The restriction 19 in this embodiment takes the form of a step or shoulder which extends radially into the bore 13 to define an intermediate bore section 25 of narrower inner diameter than that of the upper and lower sections 21, 23 (see FIGURE 4). The restriction 19 in the bore 13 is resiliently deformable such that, on application of a downward force thereon, it is able to be deflected downwardly towards the lower open end 17 and, on release of the downward force, it returns to its undeformed position. This allows the piston part 5 to be held in place in the sleeve part 3 in different sliding positions, and for a seal to be formed between the sleeve and piston parts 3, 5.

The sleeve part 3 is preferably made from a plastics material, for instance by a moulding process, such as injection moulding or micro-moulding.

The sleeve part 3 may have a outer diameter in the range of substantially 2-5mm, preferably substantially 3mm, a length in the range of substantially 5-6mm, and an inner diameter of substantially 1-3mm, preferably substantially 2mm.

Turning now to the piston part 5, this has a shank 29 of a general cylindrical cross section. The shank 29 has an upper section 31, a lower section 33 of smaller outer diameter than the upper section, and a flared section 35 connecting the upper and lower sections 31, 33. A series of longitudinal grooves or flutes 37 is circumferentially arranged about a lower end portion 34 of the upper shank section 31.

The upper section 31 of the shank 29 has an outer diameter which is the same, or, more typically, greater than, the inner diameter of the intermediate section 25 of the bore 13 in the sleeve part 3. Thus, the upper section 31 of the shank 29 fits in the intermediate section 25 with an interference fit, the resiliently deformable nature of the restriction 19 facilitating the formation of the interference fit, especially when the outer diameter of the upper section 31 of the shank 29 is greater than the inner diameter of the intermediate section 25 of the bore 13.

At an upper end of the shank 29 there is provided a co-axially arranged piston head 39 of larger outer diameter than the shank 29.

The piston part 5 is also preferably made from a plastics material; for instance by a moulding process, such as injection moulding or micro-moulding.

In use, the piston part 5 is first slidably mounted in the sleeve part 3 in a filling position shown in FIGURE 1. In the filling position, the upper section 31 of the shank 29 of the piston part 5 is slidably received in the intermediate section 25 of the bore 13 so as to be held in frictional engagement therewith such that the longitudinal grooves 37 place the upper and lower bore sections 21,23 in fluid communication with one another. In this regard, it will be noted that the longitudinal grooves 37 have a longer longitudinal dimension than that of the intermediate section 25 of the bore 13. Placing the piston part 5 in the filling position spaces the piston head 39 above the upper open end 15 of the bore 13, as further shown in FIGURE 1. In this way, an inlet path 41 into the upper section 21 of the bore 13 is defined.

With the piston part 5 in its filling position, application of a vacuum to the lower open end 17 of the sleeve part 3 draws powder particles 2 from a particle cloud in the exterior environment around the capsule 1 into the upper bore section 21 through the inlet path 41 as a result of the vacuum pressure acting in the upper bore section 21 through the longitudinal grooves 37. This is shown diagrammatically in FIGURE 1 by the arrows A.

The longitudinal grooves 37 are sized such that the powder particles 2 are occluded therein. This does not prevent the vacuum from creating the negative pressure in the upper bore section 21 in the filling position, but prevents the powder 2 from seeping from the upper bore section 21 to the lower bore section 23. As an example, the grooves 37 may have a depth in the range of substantially 0.005-0.01 mm, preferably substantially 0.007 mm.

Once the upper bore section 21 has been filled with the required dose of powder 2, for example a unit dose of a pharmaceutical powder, the vacuum is removed and the piston part 5 slid downwardly in the sleeve part 3 to a sealed position shown in FIGURE 3. The sliding movement of the piston part 5 to the sealed position results in:-

- (i) The longitudinal grooves 37 moving out of the intermediate bore section 25 into the lower bore section 23 to bring the upper shank section 31 into sealing, frictional engagement with the intermediate section 25.
- (ii) The piston head 39 being brought into sealing engagement with the countersunk entrance 27 of the bore 13.

This prevents or inhibits ingress of air or moisture into the upper bore section 21 and prevents egress of the powder 2 from the capsule 1. So, in the sealed position the powder 2 drawn into the upper bore section 21 is sealably contained therein.



When the dose of powder 2 in the upper bore section 21 is required to be discharged, the piston part 5 is slid upwardly to a discharge position shown in FIGURE 4. In the discharge position of the piston part 5, the piston head 39 is spaced upwardly of the upper open end 15 of the sleeve part 3 and the lower section 33 of the shank 29 is positioned in the intermediate bore section 25. In this way, an airflow path indicated by the arrows B is provided which enables the powder 2 in the upper bore section 21 to be discharged from the capsule 1 out of the upper open end 15 of the sleeve part 3. The powder 2 may be discharged in this way by application of a positive air pressure to the bore 13 of the sleeve part 3 through the lower open end 17.

It will be understood that the embodiment described hereinabove may be varied and modified in many different ways and adopt other guises within the scope of the appended claims. With this in mind, the use of reference numerals in the appended claims is for illustration only, and not meant to have a limiting effect on the scope of the claims. Finally, the use of prefixes such as "substantially" and "generally" to numeric values or geometries in the specification is meant to include the exact numeric value or geometry.

## CLAIMS

1. A capsule (1) for a powder (2) having a body which is provided with an internal chamber (21) to hold the powder and first and second openings (17, 15)  
5 to an exterior environment, the body adapted to be displaced from a filling state, in which the first and second openings are placed in fluid communication with one another through the internal chamber thereby enabling a vacuum to be applied at the first opening (17) to create an airflow through the body from the second opening (15) to the first opening which is able to entrain powder in the  
10 exterior environment into the internal chamber for filling thereof, to a sealing state in which the internal chamber is sealed from the exterior environment so as to retain the powder held therein.
2. The capsule of claim 1 in which the filling and sealing states are,  
15 respectively; expanded and contracted states of the body.
3. The capsule of claim 1 or 2 wherein in the filling state of the body the first opening is partially obstructed to an extent which permits airflow therethrough, but which becomes occluded with powder entrained in the airflow.  
20
4. The capsule of claim 1, 2 or 3 in which the body is a multi-part structure in which parts (3, 5) of the body are moved relative to one another to bring the body to its filling and sealing states.
- 25 5. The capsule of claim 4 in which the body is assembled in both the filling and sealing states.
6. The capsule of claim 4 or 5 in which the body has first and second parts (5, 3) which are moved relative to one another to bring the body to its filling and  
30 sealing states.
7. The capsule of claims 5 and 6 wherein in the filling and sealing states the first part is mounted to the second part.

8. The capsule of claim 6 or 7 wherein in the sealing state the first part is disposed in a first position relative to the second part in which it sealingly closes the first and second openings, and wherein in the filling state the first part is disposed in a second position relative to the second part in which it opens the first and second openings.

9. The capsule of any one of claims 6 to 8 when appended to claim 3 in which the first part partially obstructs the first opening in the filling state.

10. The capsule of claim 9 in which the first part is partially plugged in the first opening in the filling state.

11. The capsule of claim 10 in which the first part has a plug section (34) which is located in the first opening in the filling state, the plug section having an outer surface (37) which, in the filling state, is at least in part spaced from an inner surface of the first opening.

12. The capsule of claim 11 in which the outer surface has first and second outer surface portions, wherein in the filling state the first outer surface portion (37) is spaced from the inner surface of the first opening and the second outer surface portion abuts the inner surface of the first opening.

13. The capsule of claim 12 in which the first outer surface portion corresponds to one or more channels (37) in the outer surface of the plug section.

14. The capsule of claim 11, 12 or 13 in which the plug section is a first plug section and the first part has a second plug section which sealingly plugs the first opening in the sealing state.

15. The capsule of claim 14 in which the body is moved from the filling state to the sealing state by movement of the first part in a first direction relative to the

second part, the first plug section being disposed, in use, on the first part in the first direction relative to the second plug section.

16. The capsule of claim 14 or 15 in which the first and second plug sections are contiguously arranged.

17. The capsule of claim 8 or any one of claims 9 to 16 when appended to claim 8 in which the first part sealingly plugs the second opening in the sealing state.

18. The capsule of any one of claims 6 to 17 in which the first opening is formed in the second part.

19. The capsule of any one of claims 6 to 18 in which the second opening is formed in the second part.

20. The capsule of claims 18 and 19 in which the second part is a sleeve part with an internal passageway (21) which connects the first and second openings.

21. The capsule of claim 20 in which the first opening is formed by a restriction (25) in the passageway.

22. The capsule of claim 21 in which the restriction is formed by an inwardly directed shoulder (25) in the passageway.

23. The capsule of any one of claims 20 to 22 in which the second opening is formed at an end of the internal passageway.

24. The capsule of any one of claims 6 to 23 in which the first part is mounted in the second part for sliding movement relative thereto.

25. The capsule of any one of claims 6 to 24 in which the internal chamber is defined between the first and second parts.

26. The capsule of any one of claims 20 to 23 in which the first part is slidably mounted in the passageway and the internal chamber is defined between the inner surface of the passageway and the outer surface of the first part.

5

27. The capsule of any one of claims 6 to 26 wherein in the filling state the first part extends through the second opening to leave a gap therebetween for ingress of the entrained powder into the internal chamber and wherein in the sealing state the first part is moved into sealing relation in the second opening.

10

28. The capsule of claim 27 in which the first part has a cap section (39) which, in the filling state, is spaced exteriorly of the second opening, but which in the sealing state is sealingly seated in the second opening.

15 29. The capsule of claim 28 when appended to claim 11 in which the first part has a shank section (29) connecting the cap section to the plug section.

20 30. The capsule of any one of claims 6 to 29 in which the first and second parts are further movable relative to one another to bring the body from the sealing state to a discharging state in which an airflow is able to be produced through the body from the first opening to the second opening to entrain the powder in the internal chamber into the exterior environment.

25 31. The capsule of claim 30 when appended to claim 11 wherein the first part has a section with a transverse dimension which is less than the corresponding dimension of the plug section, the section being located with respect to the plug section such that in the discharging state it is brought into registration with the first opening.

30 32. The capsule of any one of the preceding claims comprising a pharmaceutical powder in the internal chamber.

33. The capsule of claim 32 having a unit dose of the pharmaceutical powder in the internal chamber.

34. The capsule of any one of the preceding claims in which the internal chamber is the sole internal chamber.

35. An inhalation device comprising one or more capsules according to claim 33 or 34.

36. A capsule for a powder substantially as hereinbefore described with reference to, and as illustrated by, the accompanying FIGURES of drawings.

## ABSTRACT

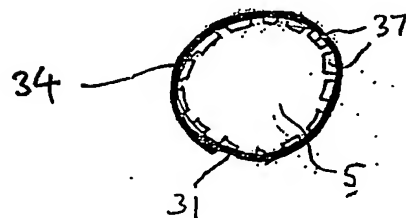
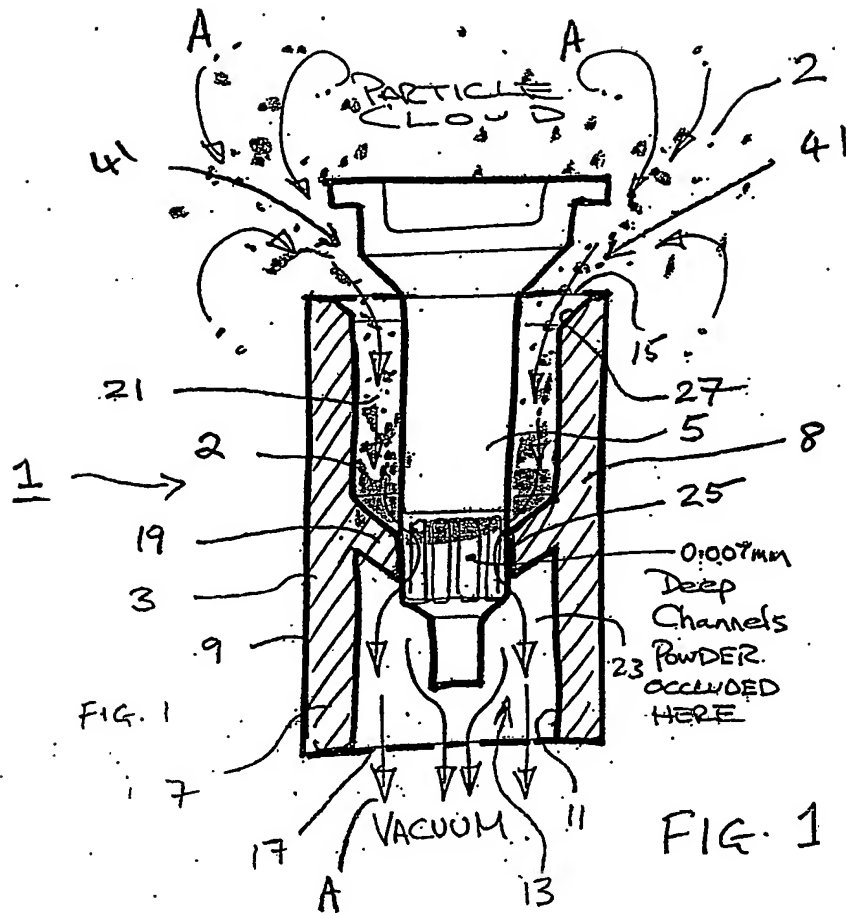
### A Capsule

5           A capsule (1) for a powder (2) has a body which is provided with an  
internal chamber (21) to hold the powder and first and second openings (17, 15)  
to an exterior environment. The body is adapted to be displaced from a filling  
state, in which the first and second openings are placed in fluid communication  
with one another through the internal chamber thereby enabling a vacuum to be  
10       applied at the first opening (17) to create an airflow through the body from the  
second opening (15) to the first opening which is able to entrain powder in the  
exterior environment into the internal chamber for filling thereof, to a sealing state  
in which the internal chamber is sealed from the exterior environment so as to  
retain the powder held therein.

15

(FIG. 1)

1/2





2/2

